



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/EP97/00269 <b>(22) International Filing Date:</b> 21 January 1997 (21.01.97) <b>(30) Priority Data:</b> 96100928.9 23 January 1996 (23.01.96) EP <b>(34) Countries for which the regional or international application was filed:</b> AT et al. <b>(71) Applicant (for all designated States except US):</b> CHEMISCH ADVIESBUREAU DRS. J.C.P. SCHREUDER B.V. [NL/NL]; P.O. Box 430, NL-3740 AK Baarn (NL). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> SCHREUDER, Johannes [NL/NL]; P.O. Box 430, NL-3740 AK Baarn (NL). <b>(74) Agents:</b> DIEHL, Hermann, O., Th. et al.; Flüggenstrasse 13, D-80639 München (DE).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> COMPOSITION FOR TREATING SKIN AFFECTIONS AND PROCESS FOR ITS PREPARATION  <b>(57) Abstract</b>  There is described a multifunctional composition for the treatment of chapped, sore and/or inflamed skin parts, comprising at least the following ingredients: (a) an oil fraction comprising straight or branched paraffinic oils, having from 10 to 60 carbon atoms in the chain; (b) an emulsifying system mainly comprising (b,i) mono- and/or diglycerides of high unsaturated and saturated fatty acids, and (b,ii) ethoxylated triglycerides, esterified with fatty acids; (c) vitamin E, or a derivative thereof; (d) methionine; (e) a pH regulating system; (f) a stabilizer consisting of montmorillonite; (g) water ad 100 % by weight, and the preparation and use of said composition.		

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COMPOSITION FOR TREATING SKIN AFFECTIONS AND PROCESS  
FOR ITS PREPARATION.

The invention relates to a composition for treating skin affections, to a process for its preparation, and to the application of said composition. In particular the invention relates to a multifunctional composition for the treatment of chapped, sore and/or inflamed skin parts such as lips, nose opening edges, eyelids and the like, while such composition does not contain ingredients which may disturb the biological equilibrium of said skin part.

Specifically, the composition of the invention heals, relieves and softens chapped, sore or inflamed lips, nose opening edges, eyelids and the like, affected by a Herpes Simplex virus type, such as fever blister and/or affections by winter weather and/or intensive sunshine.

The before mentioned affections can also be caused by flu or menstruation.

Many compositions have already been proposed for this purpose in the course of the last decade. However, the up to now available prior art compositions have the disadvantage that they cause a burning, irritated and/or inflamed feeling, usually caused by constituents which significantly disturb the biological equilibrium of the affected skin parts. As a consequence, said prior art compositions usually did not relieve the irritation or even pain, and certainly did not heal the affected skin in an efficient way.

Therefore one object of the present invention is to provide a multifunctional composition for the treatment of chapped, sore and/or inflamed skin parts such as lips, nose opening edges, eyelids and the like, which during application does not cause a burning, irritated and/or inflamed feeling and which facilitate an almost immediate relief and healing, and the constituents of which do not disturb the biological equilibrium of the affected skin parts.

Another object of the present invention is to provide a process for the preparation of said composition.

5 As a result of extensive and lengthy research and experimentation, such compositions have surprisingly been found.

10 Accordingly, the present invention provides a multifunctional composition for the treatment of chapped, sore and/or inflamed skin parts such as lips, nose opening edges, eyelids and the like, characterised by at least the following ingredients:

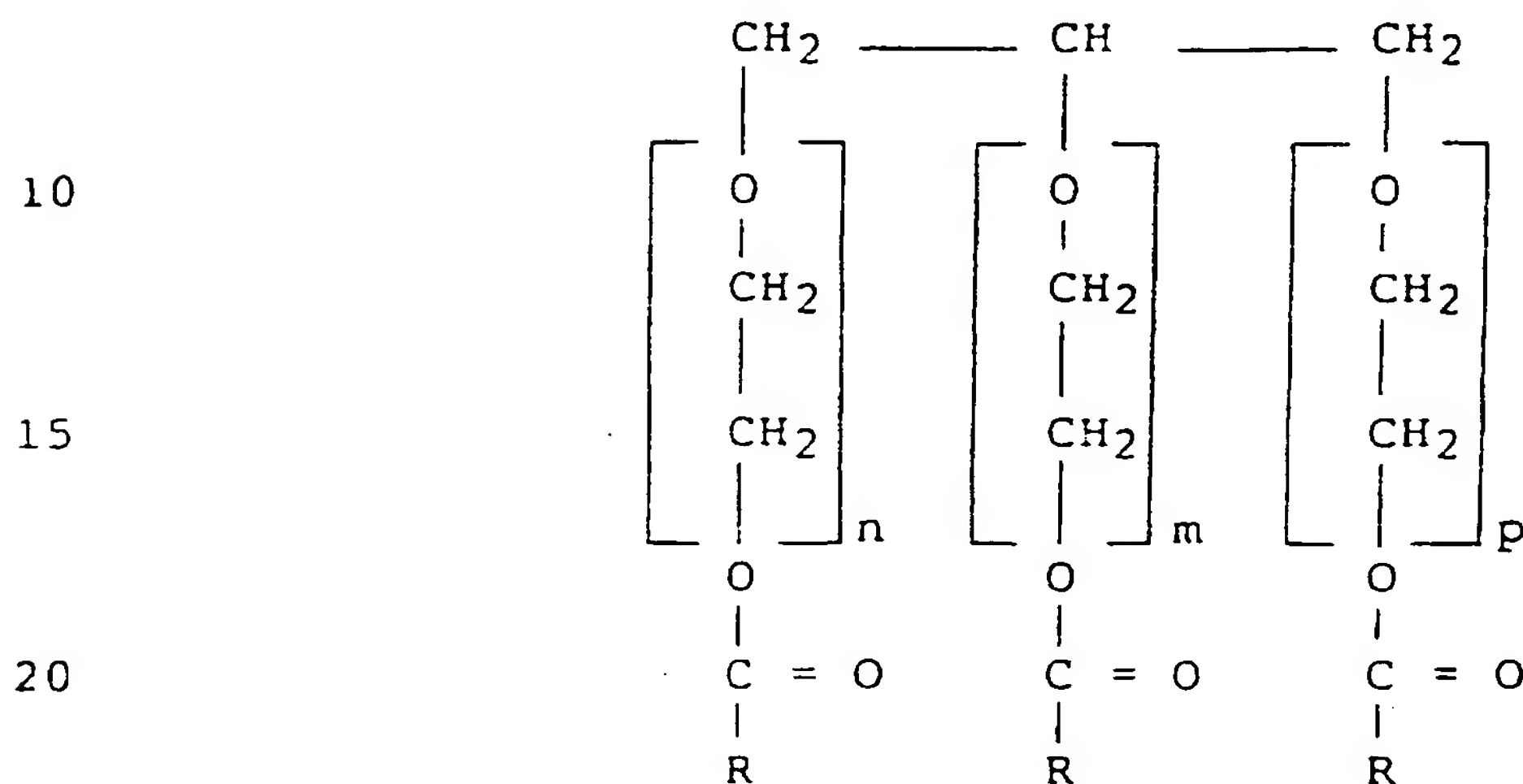
15 (a) An oil fraction comprising straight or branched paraffinic oils, having from 10 to 60 carbon atoms in the chain, and preferably from 15 to 25 carbon atoms, in an amount of from 10 to 60 % by weight, and preferably from 15 to 25 % by weight, relative to the weight of the  
20 complete composition, having a boiling range between 100 and 500°C at atmospheric pressure and a viscosity of preferably at most 35 mm<sup>2</sup>/s, preferably of at most 30 mm<sup>2</sup>/s, at 25°C, while the paraffinic oils may optionally  
25 be mixed with esters of higher natural fatty acids, which are preferably unsaturated, and of higher natural aliphatic alcohols, which are preferably unsaturated, of at most 20 carbon atoms in the chain, in an amount of from 0 to 2 % by weight, and preferably from 0.5 to 2 %  
30 by weight, relative to the weight of the complete composition;

(b) An emulsifying system mainly comprising

35 (b,i) mono- and/or diglycerides of higher unsaturated and saturated fatty acids, in an amount of from 0.5 to 3 % by weight, relative to the weight of

the complete composition, e. g. Tegomuls (trademark), and

(b,ii) ethoxylated triglycerides esterified with fatty acids, according to the general formula



wherein n, m and p represent the same or different integers of from 0 to 20, under the condition that at least one of the symbols n, m and p has a value of from 5 to 20, preferably from 7 to 15, and wherein R represents the same or different saturated or unsaturated, and preferably the same unsaturated hydrocarbon residue, derived from vegetable or animal oil (e.g. Tagat TO). The weight ratio between the amount of mono- and/or diglycerides on the one hand and of the ethoxylated triglycerides on the other hand may vary from 10 to 100 parts by weight of mono- and/or diglycerides per part by weight of ethoxylated triglycerides and preferably from 15 to 50 parts by weight of mono- and/or diglycerides per part by weight of ethoxylated triglycerides, whereas the amount of the complete emulsifying system, relative to the weight of the complete composition, may vary from 0.5 to 3.5 % by weight and preferably from 2 to 3 % by weight, relative to the weight of the total composition.

(c) Vitamin E, or a derivative thereof which may easily provide vitamin E itself by conversion on the affected skin, such as Covitol (trademark), in an amount of from 0.1 to 5 % by weight, and preferably from 0.5 to 4 % by weight, and most preferably from 1 to 3 % by weight, relative to the weight of the total composition;

(d) Methionine, in the form of its L or D isomer or mixtures thereof, preferably L-methionine, or a derivative thereof which may easily provide methionine by conversion on the affected skin, in an amount of from 0.1 to 5 % by weight and preferably from 0.5 to 3 % by weight and most preferably from 1 to 2 % by weight, relative to the weight of the complete composition;

(e) A pH regulating system to adjust the pH of a present aqueous phase, including at least demineralized water and methionine, to be in the range of from 4.4 to 5.0 and more preferably from 4.5 to 4.9, comprising preferably citric acid, zinc carbonate and sodium hydroxide, or citric acid, zinc carbonate and potassium hydroxide, each of the components occurring in an amount of from 0.05 to 2.5 % by weight, relative to the weight of the complete composition.

More preferably citric acid, zinc carbonate and sodium hydroxide occur in amounts of from 0.5 to 2 % by weight, from 0.05 to 0.2 % by weight and from 0.5 to 1 % by weight, respectively, relative to the weight of the complete composition.

The pH of the final complete composition is adjusted by said pH regulating system to the range of from 4.8 to 5.1 with citric acid or sodium hydroxide.

(f) A stabilizer, consisting of at least one montmorillonite, the free oxygen sites of which are occupied by quaternary groups (quaternary modified montmorillonites). Examples of such stabilizers which are preferably included are Bentone (trademark) or Propoloid (trademark). Said stabilizers are included in the composition in amounts of from 0.1 to 1.5 % by weight and preferably from 0.5 to 0.7 % by weight, relative to the weight of the complete composition.

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(g) Water ad 100 % by weight.

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Preferably demineralized water is used in amounts of from 65 to 75 % by weight, relative to the weight of the complete composition.

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In addition to the before mentioned primary indispensable ingredients, one or more secondary ingredients also can be present in the complete compositions, such as:

(h) At least one preservative.

-25

Preferably different types are present in the continuous ultimately formed oily phase.

For example esters of parahydroxy benzoic acid may occur in the oily phase as well as in the aqueous phase.

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Preferably the methyl and/or the (iso)propyl ester is present in an amount of from 0.1 to 1 % by weight and most preferably in amounts from 0.5 to 0.7 % by weight, relative to the weight of the complete composition.

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Most preferably mixtures of methyl, propyl and butyl p-hydroxybenzoate are used, e.g. Phenonip (trademark).



It will be appreciated by a person skilled in the art, that these before mentioned preservatives may be completely or partially replaced by other preservatives, e.g. Germall II (trademark) or Hydroconserv (trademark), and if so, said other preservatives are present preferably in an amount of from 0.1 to 0.5 % by weight.

More preferably the preservatives occur in the aqueous phase in a total amount of from 0.3 to 0.4 % by weight;

(i) Glycerol, in an amount of from 1 to 4 % by weight and more preferably from 1 to 3 % by weight.

(j) A gel forming agent, such as carraghenate, preferably consisting of a polysaccharide with sulphonic acid residues, and preferably a gel forming agent of natural origin such as one derived from seaweeds. The sulphonic acid residues have optionally been converted into salts or esters of glycol, propylen glycol and glycerol (resulting in the so-called modified carraghenates).

The gel forming agent, e. g. the carraghenates, in amounts of from 0.1 to 5 % by weight, relative to the weight of the complete composition and preferably from 0.5 to 2 % by weight, cause a gel structure in the final composition. Such a complete composition shows a viscosity of 200 to 5000 mPa·s (centipoises) at 25°C, enabling an adequate application of the composition.

It will be appreciated by a person skilled in the art that the carraghenate may be completely or partially replaced by alternative gel forming means, such as carboxy methyl cellulose, esterified by polyacrylic acid e. g. Carbopol (trademark), or hydroxy ethyl cellulose, in amounts which provide the viscosity values in the above range.



(k) Perfume, in an amount of from 0.1 to 2 % by weight, preferably 0.1 to 0.3 % by weight, relative to the weight of the complete composition. Examples of such perfumes are sage oil or jacaranda.

(l) at least one protein, obtainable from aqueous extraction of plants, such as aloe vera, in amounts of from 0.1 to 0.5 % by weight, relative to the weight of the complete composition, and preferably from 0.1 to 0.3 % by weight.

The compositions according to the present invention as specified hereinbefore, are characterized by a relatively low viscosity and high stability, which guarantees an easy application, without a "greasy" feeling or stickiness, due to the fast penetration into the skin tissue, and moreover by a healing, relieving and softening activity.

Another aspect of the present invention is formed by a process for the preparation of the hereinbefore specified compositions.

The complete continuous oily phase is prepared in one or more steps of said process, composed of oil fractions, the optional esters of fatty acids and alcohols, the emulsifying system, the stabilizer, vitamin E or a derivative thereof and the optional preservative, wherein in one or more separate steps at least one dispersed aqueous phase is prepared, composed of demineralized water, citric acid or a citrate, zinc carbonate and sodium or potassium hydroxide, methionine, glycerol, gel forming agent, protein, and preservative and perfume.

The composition according to the present invention is prepared by composing both phases and mixing them together at a temperature of 10 to 40°C, followed by additional stirring

and homogenizing until an average particle size of the dispersed aqueous phase of at most 5  $\mu$  and preferably smaller than 3  $\mu$  is reached, while the pH of the final complete composition is adjusted within the range of from 4.8 to 5.1.

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According to a preferred embodiment of the process to prepare the composition of the present invention, in a first step the oil fraction, the optional esters of unsaturated fatty acids and alcohols, the emulsifying system and the stabilizer are mixed and homogenized at a temperature from 60 to 90°C, whereafter the homogeneous mixture is cooled back to a temperature of at most 30°C.

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The cooled mixture is mixed in a second step with vitamin E or a derivative thereof which can easily be transformed into said vitamin, and with the perfume, until a homogeneous mixture is obtained.

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The aqueous phase is normally prepared at a temperature of from 10 to 40°C and preferably from 20 to 30°C by subsequent addition of demineralized water in an amount of about one third of the total amount in the final composition, of the citric acid, of zinc carbonate and of sodium or potassium hydroxide under gently stirring until complete dissolution. If necessary the pH of the homogeneous solution is adjusted to the range of from 4.6 to 4.8 by addition of sodium or potassium hydroxide or citric acid. To this aqueous solution the remainder of the desired total amount of water, methionine, glycerol, carraghenate, preservative and protein are added whereafter the pH is again adjusted to the range of from 4.5 to 4.8.

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The finally obtained aqueous phase is added to the oily phase under stirring vigorously and subsequent homogenizing at a temperature in the range of from 10 to 40°C and preferably from 20 to 30°C, whereafter the pH of the complete

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dispersion, having dispersed aqueous phase particles of an average size of at most 5  $\mu$ , is in the range of from 4.9 to 5.1.

5 Another aspect of the present invention is formed by the application of the before specified composition, i. e. the treatment of the chapped, sore and/or inflamed skin of lips and nose opening edges, eyelids and the like, with the hereinbefore specified composition.

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Such an application comprises a method being usual for said compositions, characterized by application and evenly spreading the composition on the skin area involved, in an amount of from 20 to 100 ml/m<sup>2</sup> skin area.

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This treatment should preferably be performed 2 to 3 times a day.

20 The invention is illustrated by the following examples, however without restricting its scope to these specific embodiments.

Example 1

Under stirring and heating to a temperature of 80°C the  
5 following ingredients are combined:

10		paraffinic oil I, boiling range 295-390°C Shell Ondina 15 (trademark)	10.000 kg
		paraffinic oil II, boiling range 290-500°C Shell Ondina 68 (trademark)	6.000 kg
15		mono- and diglycerides, Tegomuls SB (trademark)	2.280 kg
20		quaternary modified montmorillonite, Bentone 38 (trademark)	0.660 kg
	Batch I	oleyl decalate, Cetiol V (trademark)	1.000 kg
25		ethoxylated triglycerides, Tagat TO (trademark)	0.050 kg

30 The homogeneous mixture is cooled to 30°C and mixed with

	Batch II	vitamin E, Covitol (trademark)	2.000 kg
		perfume (sage oil)	0.125 kg
35		perfume (jacaranda)	0.075 kg

to a homogeneous mixture.

An aqueous phase is prepared by mixing together:

5	Batch III	water	21.417 kg
		citric acid	1.133 kg
		zinc carbonate BCP49	0.700 kg
		sodiumhydroxide (97 %)	0.150 kg

whereafter the pH of the aqueous solution is adjusted with  
either citric acid or sodium hydroxide to a pH of from 4.60  
10 to 4.80, and

15	Batch IV	water	49.610 kg
		L-methionine	1.000 kg
		glycerol 1.26	2.000 kg
		carraghenate, Aubygum X2 (trademark)	1.000 kg
		preservatives	0.600 kg
		protein, aloe vera	0.200 kg

The batches III and IV are combined and mixed with the  
20 mixture of batches I and II under vigorously stirring and  
homogenizing until an average particle size of the dispersed  
phase of 3  $\mu$  is obtained, whereafter the pH of the complete  
composition was 5.0.

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### Example 2

According to the same procedure as described in Example 1, a  
composition was prepared from the following ingredients:

30	Batch I	paraffinic oil I	14.700 kg
		paraffinic oil II	3.200 kg
		mono- and diglycerides	2.100 kg
		quaternary modified montmorillonite	0.650 kg
		ethoxylated triglycerides	0.050 kg
35	and		

	Batch II	vitamin E	2.200 kg
		perfume (sage oil)	0.140 kg
		perfume (jacaranda)	0.075 kg
	and		
5	Batch III	water	21.340 kg
		citric acid	1.130 kg
		zinc carbonate	0.700 kg
		potassium hydroxide (97 %)	0.155 kg
	and		
10	Batch IV	water	48.105 kg
		L-methionine	1.300 kg
		glycerol	1.800 kg
		carraghenate	1.200 kg
		preservatives	0.700 kg
15		protein	0.400 kg

Example 3

According to the same procedure as described in Example 1, a composition was prepared from the following ingredients:

	Batch I	paraffinic oil I	12.200 kg
		paraffinic oil II	3.200 kg
		mono- and diglycerides	2.200 kg
25		ethoxylated triglycerides	0.055 kg
		quaternary modified montmorillonite	0.645 kg
	and		
	Batch II	vitamin E	2.100 kg
		perfume (sage oil)	0.140 kg
30		perfume (jacaranda)	0.080 kg
	and		
	Batch III	water	21.500 kg
		citric acid	1.130 kg
		zinc carbonate	0.700 kg
35		sodium hydroxide	0.160 kg
	and		

5	Batch IV	water	49.690 kg
		L-methionine	1.500 kg
		glycerol	2.500 kg
		carraghenate	1.300 kg
		preservative	0.600 kg
		protein	0.300 kg

Example 4

10 According to the same procedure as described in Example 1, a composition was prepared from the following ingredients:

15	Batch I	paraaffinic oil I	12.000 kg
		paraaffinic oil II	3.400 kg
		mono- and diglycerides	2.200 kg
		ethoxylated triglycerides	0.060 kg
		quaternary modified montmorillonite	0.640 kg
and			
20	Batch II	vitamin E acetate, D-isomer	2.300 kg
		perfume (sage oil)	0.400 kg
		perfume (jacaranda)	0.080 kg
and			
25	Batch III	water	21.900 kg
		citric acid	1.130 kg
		zinc carbonate	0.700 kg
		sodium hydroxide (97 %)	0.160 kg
and			
30	Batch IV	water	50.250 kg
		D,L-methionine	2.000 kg
		glycerol	2.000 kg
		preservative	0.600 kg
		protein	0.380 kg



The hereinbefore specified compositions show a high stability and a fast healing, relieving and softening activity when applied on sore, chapped and/or inflamed skin of lips and nose opening edges.

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Claims

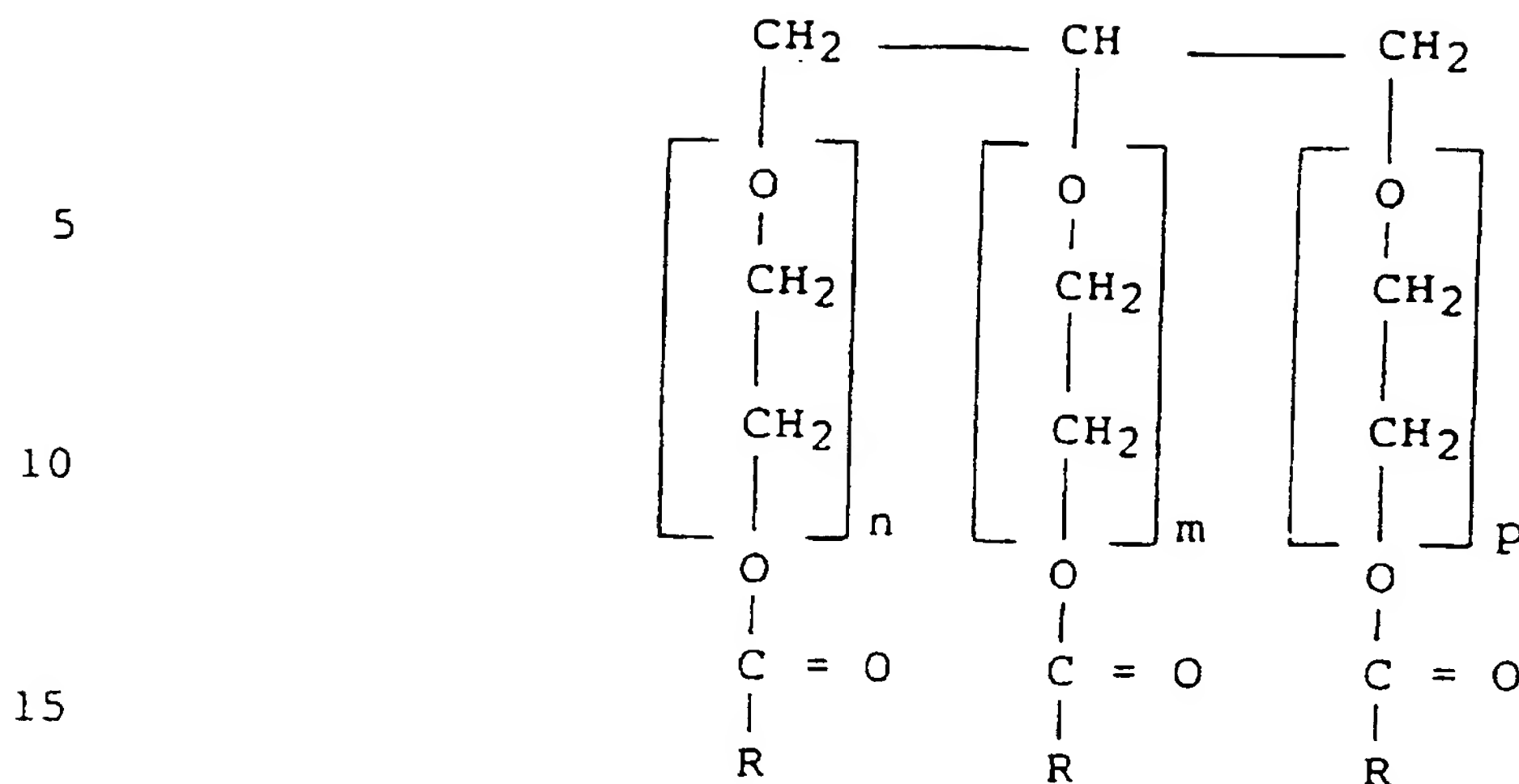
1. Multifunctional composition for the treatment of chapped, sore and/or inflamed skin parts such as lips, nose opening edges, eyelids and the like, characterized by at least the following ingredients:

(a) An oil fraction comprising straight or branched paraffinic oils, having from 10 to 60 carbon atoms in the chain, in an amount of from 10 to 60 % by weight, relative to the weight of the complete composition, having a boiling range between 100 and 500°C at atmospheric pressure and a viscosity of at most 35 mm<sup>2</sup>/s at 25°C, while the paraffinic oils may optionally be mixed with esters of higher natural fatty acids, which are preferably unsaturated, and of higher natural aliphatic alcohols, which are preferably unsaturated, of at most 20 carbon atoms in the chain, in an amount of from 0 to 2 % by weight, relative to the weight of the complete composition;

(b) an emulsifying system mainly comprising

(b,i) mono- and/or diglycerides of higher unsaturated natural fatty acids, in an amount of from 0.5 to 3 % by weight, relative to the weight of the complete composition, and

(b,ii) ethoxylated triglycerides esterified with fatty acid, according to the general formula



wherein n, m and p represent the same or different integers of from 0 to 20, under the condition that at least one of the symbols n, m and p has a value of from 5 to 20, preferably from 7 to 15, and wherein R represents the same or different saturated or unsaturated, and preferably the same unsaturated hydrocarbon residue, derived from vegetable or animal oil,

whereby the weight ratio between the amount of mono- and/or diglycerides on the one hand and of the ethoxylated triglycerides on the other hand may vary from 10 to 100 parts by weight of mono- and/or diglycerides per part by weight of ethoxylated triglycerides, whereas the amount of the complete emulsifying system, relative to the weight of the complete composition, may vary from 0.5 to 3,5 % by weight,

(c) vitamin E, or a derivative thereof which may easily provide vitamin E itself by conversion on the affected skin in an amount of from 0.1 to 5 % by weight, relative to the weight of the total composition;

(d) methionine, in the form of its L or D isomer or mixtures thereof, preferably L-methionine, or a derivative thereof which may easily provide methionine by conversion on the affected skin, in an amount of from 0.1 to 5 % by weight, relative to the weight of the complete composition;

(e) a pH regulating system to adjust the pH of a present aqueous phase including at least demineralized water and methionine, to be in the range of from 4.4 to 5.0, comprising preferably citric acid, zinc carbonate and sodium hydroxide or citric acid, zinc carbonate and potassium hydroxide, each of the components occurring in an amount of from 0.05 to 2.5 % by weight, relative to the weight of the complete composition;

(f) a stabilizer consisting of at least one montmorillonite the free oxygen sites of which are occupied by quaternary groups in an amount of from 0.1 to 1.5 % by weight, relative to the weight of the complete composition;

(g) water ad 100 % by weight.

2. Composition according to claim 1, comprising

(a) an oil fraction, comprising straight or branched paraffinic oils in an amount of from 15 to 25 % by weight, mixed with esters of unsaturated higher natural aliphatic alcohols in an amount of from 0.5 to 2 % by weight;

(b) an emulsifying system mainly comprising

(b,i) mono- and/or diglycerides of higher unsaturated and saturated fatty acids, in an amount of from 0.5 to 3 % by weight,

5 (b,ii) ethoxylated triglycerides according to the general formula of claim 1 wherein n, m and p are the same or different and each has a value from 7 to 15, and R is defined as in claim 1,

0 whereby the weight ratio between the amount of mono-, and/or diglycerides and of the ethoxylated triglycerides is in the range of from 15 to 50 parts by weight of mono- and/or diglycerides per part by weight of ethoxylated triglycerides, whereas the amount of the complete emulsifying system, relative to the weight of the complete composition, is in the range of from 2 to 3.5 % by weight;

20 (c) vitamin E in an amount of from 1 to 3 % by weight, relative to the weight of the complete composition;

(d) L-methionine in an amount of from 1 to 2 % by weight;

25 (e) a pH regulating system to adjust the pH of the aqueous system to be in the range of from 4.5 to 4.9, comprising citric acid, zinc carbonate and sodium hydroxide in amounts of 0.5 to 2 % by weight, from 0.5 to 1 % by weight and 0.05 to 0.2 % by weight, respectively;

30 (f) the stabilizer in an amount of from 0.5 to 0.7 % by weight;

35 (g) water ad 100 % by weight.

3. Composition according to claims 1 or 2, comprising additionally:

5 (h) at least one preservative in an amount of from 0.1 to 1 % by weight, preferably from 0.5 to 0.7 % by weight, relative to the weight of the complete composition;

10 (i) glycerol in an amount of from 1 to 4 % by weight, preferably from 1 to 3 % by weight, relative to the weight of the complete composition;

15 (j) a gel forming agent in an amount of from 0.1 to 5 % by weight, preferably from 0.5 to 2 % by weight, relative to the weight of the complete composition;

(k) perfume in an amount of from 0.1 to 2 % by weight, relative to the weight of the complete composition;

20 (l) at least one protein, obtainable from aqueous extraction of plants, such as aloe vera, in an amount of from 0.1 to 0.5 % by weight, preferably from 0.1 to 0.3 % by weight, relative to the weight of the complete composition.

25 4. Process for the preparation of a composition according to any of claims 1 to 3, characterized by the preparation in one or more steps of the complete continuous oily phase, composed of the oil fraction, the optional esters of fatty acids and alcohols, the emulsifying system, the stabilizer, vitamin E or a derivative thereof, the perfume and the optional preservative, and by the preparation in one or more steps of at least one dispersed aqueous phase composed of demineralized water, 30 citric acid or a citrate, zinc carbonate and sodium or potassium hydroxide, methionine, glycerol, gel forming

agent, protein, and preservative, and by mixing together both phases at a temperature in the range of from 10 to 40°C, followed by additional stirring and homogenizing until an average particle size of the dispersed aqueous phase of at most 5  $\mu$ , and preferably smaller than 3  $\mu$ , is reached, while the pH of the final complete composition is adjusted within the range of from 4.8 to 5.1.

5. Process according to claim 4, characterized in that

in a first step the oil fraction, the optional esters of fatty acids and alcohols, the emulsifying system and the stabilizer are mixed and homogenized at a temperature from 60 to 90°C, whereafter the homogeneous mixture is cooled back to a temperature of at most 30°C,

whereafter the cooled mixture is mixed in a second step with vitamin E or a derivative thereof which can easily be transformed into said vitamin, and with the perfume until a homogeneous mixture is obtained;

and that the aqueous phase is prepared by subsequent addition of demineralized water in an amount of about one third of the total amount in the final composition, of citric acid, of zinc carbonate and of sodium or potassium hydroxide under gently stirring until complete dissolution, whereafter, if necessary, the pH of the homogeneous solution is adjusted to the range of from 4.6 to 4.8 by addition of sodium or potassium hydroxide or citric acid, and the remainder of the desired total amount of water, methionine, glycerol, carreghenate, preservative and protein are added to the aqueous solution, whereafter the pH is again adjusted to the range of from 4.6 to 4.8,



and that the finally obtained aqueous solution is added to the oily phase under stirring vigorously and subsequent homogenizing at a temperature in the range of from 10 to 40°C, preferably from 20 to 30°C, whereafter the pH of the complete dispersion, having dispersed aqueous phase particles of an average size of at most 5  $\mu$  is in the range of from 4.9 to 5.1.

6. Use of a composition according to any of claims 1 to 3, comprising the application and evenly spreading on chapped, sore and/or inflamed lips, nose opening edges, eyelids and the like, of said composition in an amount of from 20 to 100 ml/m<sup>2</sup> skin area.

## INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/EP 97/00269A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61K47/00 A61K7/48

According to International Patent Classification (IPC) or to both national classification and IPC.

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 203 211 A (CHEMISCH ADVIESBUREAU DRS J.C.P. SCHREUDER B.V.) 3 December 1986 see page 4, line 33 - page 5, line 3 see page 6, line 31 - line 33 see page 7 - page 9; examples 1-3 --- - / - -	1-6

☒ Further documents are listed in the continuation of text C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*R\* earlier document but published on or after the international filing date
- \*I\* documents which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)
- \*U\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*E\* document member of the same patent family

Date of the actual completion of the international search

9 June 1997

Date of mailing of the international search report

20.06.97

Name and mailing address of the ISA

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Authorized officer

Boulois, D

# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/EP 97/00269

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CHEMICAL ABSTRACTS, vol. 100, no. 18, 30 April 1984 Columbus, Ohio, US; abstract no. 144838k, "Cosmetics containing vitamin E analogs and Aloe extracts for skin cracking control" page 352; column 1; XP002006657 see abstract	1-6
A	& PATENT ABSTRACTS OF JAPAN vol. 8, no. 102 (C-222), 12 May 1984 & JP 59 016816 A (RAION KK), 28 January 1984, see abstract	1-6
A	& DATABASE WPI Section Ch, Week 8410 Derwent Publications Ltd., London, GB; Class B03, AN 84-59244 & JP 59 016 816 A (LION CORP.) , 28 January 1984 see abstract	1-6
A	--- EP 0 007 120 A (CHEMISCH ADVIESBUREAU DRS J.C.P. SCHREUDER) 23 January 1980 see page 4, line 11 - line 21 see page 12; example 5 see page 12, line 32 - line 34 ---	1
A	--- EP 0 138 262 A (SCHREUDER J.C.P.) 24 April 1985 see page 2, line 23 - line 27 -----	1

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 97/00269

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(1)(a) for the following reasons:

1. ☒ Claims Nos.: 6  
because they relate to subject matter not required to be searched by this Authority, namely:  
Remark: Although claim(s) 6  
is(are) directed to a method of treatment of the human/animal  
body, the search has been carried out and based on the alleged  
effects of the composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/EP 97/00269

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 203211 A	03-12-86	JP 61293918 A US 5032408 A	24-12-86 16-07-91
EP 7120 A	23-01-80	AT 2478 T CA 1138292 A JP 55027384 A US 4263284 A	15-03-83 28-12-82 27-02-80 21-04-81
EP 138262 A	24-04-85	US 4721705 A	26-01-88

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